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TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT
REPELLENT A13-38281..(U) ARMY ENVIRONMENTAL HYGIENE
AGENCY ABERDEEN PROVING GROUND MD J V WADE ET AL.

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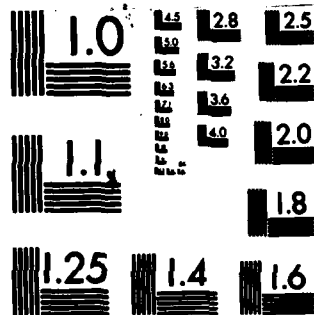
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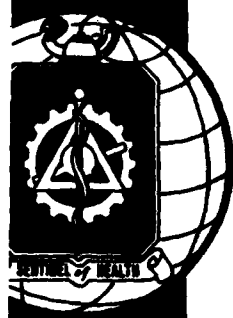




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**UNITED STATES ARMY
ENVIRONMENTAL HYGIENE
AGENCY**

ABERDEEN PROVING GROUND, MD 21010

TOPICAL HAZARD EVALUATION PROGRAM
OF
CANDIDATE INSECT REPELLENT
AI3-38281
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICAL
STUDY NO. 75-51-0422-84
FEBRUARY - NOVEMBER 1983

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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) USDA Proprietary Chemical Eye Irritation A13-38281 Skin Irritation Guinea Pig Sensitization Topical Hazard Evaluation Program		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Chemical A13-38281 did not produce primary irritation of the intact skin or of the skin surrounding an abrasion. It was noninjurious to the eyes of rabbits. Chemical A13-38281 produced a slight sensitization reaction in 3 of the 10 guinea pigs tested.		

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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

CPT(P) Wade/cvc/AUTOVON
584-3980

REPLY TO
ATTENTION OF

HSNB-OT/WP

24 FEB 1984

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellent
AI3-38281, US Department of Agriculture Proprietary Chemical,
Study No. 75-51-0422-84, February - November 1983

Executive Secretary
Armed Forces Pest Management Board
Forest Glen Section, WRAMC
Washington, DC 20307

EXECUTIVE SUMMARY

The purpose, essential findings, and major recommendations of the inclosed report follow:

a. Purpose. The purpose of this program is to provide guidance for further entomological testing of candidate insect repellent AI3-38281 by means of laboratory animal studies using New Zealand White rabbits and albino Hartley guinea pigs.

b. Essential Findings. Chemical AI3-38281 did not produce primary irritation of the intact skin and no more than mild irritation of the skin surrounding an abrasion. It was noninjurious to the eyes of rabbits. Chemical AI3-38281 produced a slight sensitization reaction in the guinea pig.

c. Major Recommendations. Recommend that chemical AI3-38281 be disapproved for further testing as a candidate insect repellent.

FOR THE COMMANDER:

1 Incl
as (5 cy)

in Rocking M. Attack
JOEL C. GAYDOS, M.D.
Colonel, MC
Director, Occupational and
Environmental Health

CF:
HQDA (DASG-PSP) no incl
Cdr, HSC (HSPA-P)
Comdt, AHS (HSHA-P)
Dir, Advisory Cen on TOX, MRC (2 cy)
USDA, ARS (Dr. Terrence McGovern)
USDA, ARS-Southern Region
Cdr, USAHRDC, [SGRD-DPM/LTC(P) Reinert?]



DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

REPLY TO
ATTENTION OF

HS HB-OT/WP

TOPICAL HAZARD EVALUATION PROGRAM
OF
CANDIDATE INSECT REPELLENT
AI3-38281
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICAL
STUDY NO. 75-51-0422-84
FEBRUARY - NOVEMBER 1983

1. AUTHORITY.

a. Letter, US Department of Agriculture - Agricultural Research, Southern Region, Insects Affecting Man and Animals Research Laboratory, Gainesville, Florida, 10 February 1983.

b. Memorandum of Understanding between the US Army Environmental Hygiene Agency; the US Army Health Services Command; the Department of the Army, Office of The Surgeon General; the Armed Forces Pest Control Board; and the US Department of Agriculture, Agricultural Research, Science and Education Administrations; titled Coordination of Biological and Toxicological Testing of Pesticides, effective 23 January 1979.

2. REFERENCE. Toxicology Division Standing Operating Procedures, US Army Environmental Hygiene Agency (USAEHA), 1981.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of candidate insect repellent AI3-38281, US Department of Agriculture Proprietary Chemical.

4. SUMMARY OF FINDINGS. Hazard evaluations of candidate insect repellent AI3-38281, US Department of Agriculture (USDA) Proprietary Chemical, were conducted by this Agency using New Zealand White rabbits for skin and eye studies and albino Hartley guinea pigs for sensitization testing. A tabular presentation of animal toxicity data developed at this Agency follows:*†

* In conducting the studies described in this report, the investigators adhered to the "Guide for the Care and Use of Laboratory Animals," US Department of Health, Education and Welfare Publication No. (NIH) 80-23, revised 1978.

† The studies reported herein were performed in animal facilities fully accredited by the American Association for the Accreditation of Laboratory Animal Care.

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Study No. 75-51-0422-84, Feb - Nov 83

TABLE. PRESENTATION OF DATA

TEST	RESULTS	INTERPRETATION
SKIN IRRITATION STUDIES		
Rabbits		
Single 24-hour application to intact and abraded skin of New Zealand White rabbits.	Chemical AI3-38281 did not produce primary irritation of the intact skin or of the skin surrounding an abrasion.	USAEHA Category I (ref Appendix A)
0.5 mL technical grade chemical applied to each of six rabbits.		
EYE IRRITATION STUDIES		
Rabbits		
Single 24-hour application of 0.5 mL technical grade chemical to one eye of each of nine New Zealand White rabbits. Three of the nine rabbits had the eye flushed with warm water for 1 minute, 25 seconds after application.	Chemical AI3-38281 was noninjurious to the eyes of rabbits.	USAEHA Category A (ref Appendix A)
SENSITIZATION STUDIES		
Guinea Pigs (Male)		
Intradermal (ID) injections of 0.1 mL of a minimally irritating concentration of the tested chemical or of dinitrochlorobenzene (DNCB) in a mixture containing 1 volume of propylene glycol and 29 volumes of saline.		
Ten test guinea pigs were given 10 sensitizing doses over a 3-week period. After a 2-week rest, they were challenged with an ID injection of the test chemical.	Challenge doses of chemical AI3-38281 produced a slight sensitization reaction in 3 of the 10 guinea pigs.	Chemical AI3-38281 produced a slight sensitization reaction under test conditions and could produce a sensitization reaction in humans.
Ten positive control guinea pigs were sensitized over 3 weeks with DNCB. After a 2-week rest, they were challenged with ID injections of DNCB.	Challenge dose of DNCB in positive control guinea pigs produced a marked sensitization reaction in 10 out of 10 guinea pigs.	DNCB produced a marked sensitization reaction indicating these guinea pigs respond to sensitizing agents.

1A known skin sensitizer.

Study No. 75-51-0422-84, Feb - Nov 83

5. CONCLUSION. Chemical AI3-38281 did not produce primary irritation of the intact skin or of the skin surrounding an abrasion. It was noninjurious to the eyes of rabbits. Chemical AI3-38281 produced a slight sensitization reaction in 3 of the 10 guinea pigs tested. These studies were monitored by the Analytical Quality Assurance Office (see Appendix B).

6. RECOMMENDATION. Disapprove USDA Proprietary Chemical AI3-38281 for further entomological testing as a candidate insect repellent (under the provisions of the Memorandum of Understanding, paragraph 1b, this report).

John V. Wade, DVM
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CPT(P), VC

Laboratory Animal
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John G. Harvey, Jr.
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APPROVED:

Maurice H. Weeks
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Chief, Toxicology Division

The US Dept. of Agriculture Proprietary Chemical Study Number would not be known by anyone in the public domain who acquired this document. The document should remain for unlimited distribution per Capt. John V. Wade, AEHA



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APPENDIX A

TOPICAL HAZARD EVALUATION PROGRAM
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING
CONSIDERED FOR ACUTE SKIN APPLICATION

CATEGORY I - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin.)

CATEGORY II - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.)

CATEGORY III - Compounds producing moderate primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin. May be used without patch testing, with extreme caution, as clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration so that its irritation potential can be reexamined using other test techniques on animals.)

CATEGORY IV - Compounds producing moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation and/or eschars. (INTERPRETATION: Should be resubmitted for testing in the form and at the intended use concentration. Upon resubmission, its irritation potential will be reexamined using other test techniques on animals. prior to possible prophetic patch testing in humans, at concentrations which have been shown not to produce primary irritation in animals.)

CATEGORY V - Compounds impossible to classify because of staining of the skin or other masking effects owing to physical properties of the compound. (INTERPRETATION: Not suitable for use on humans.)

EYE CATEGORIES:

A. Compounds noninjurious to the eye. INTERPRETATION: Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.

B. Compounds producing mild injury to the cornea. INTERPRETATION: Should be used with caution around the eyes.

C. Compounds producing mild injury to the cornea, and in addition some injury to the conjunctiva. INTERPRETATION: Should be used with caution around the eyes and mucosa.

D. Compounds producing moderate injury to the cornea. INTERPRETATION: Should be used with extreme caution around the eyes.

E. Compounds producing moderate injury to the cornea, and in addition producing some injury to the conjunctiva. INTERPRETATION: Should be used with extreme caution around the eyes and mucosa.

F. Compounds producing severe injury to the cornea and to the conjunctiva. INTERPRETATION: Should be used with extreme caution. It is recommended that use be restricted to areas other than the face.

APPENDIX B

ANALYTICAL QUALITY ASSURANCE

The Analytical Quality Assurance Office certifies the following:

a. These studies were conducted in accordance with:

(1) Standing Operating Procedures developed by the Toxicology Division, USAEHA.

(2) Title 21, Code of Federal Regulations (CFR), 1983 rev, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

(3) Proposed Rule, Pesticide Programs; Good Laboratory Practice Standards; Final Rule, 48 Federal Register (FR) 53946-539691, 29 November 1983.

b. Facilities were inspected during its operational phase to ensure compliance with paragraph a above.

c. The information presented in this report accurately reflects the raw data generated during the course of conducting these studies.



PAUL V. SNEERINGER, Ph.D.
Chief, Analytical Quality
Assurance Office